

In re Application of: *SNYDER, R.O. et al.*
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REMARKS

Applicants have filed a Petition for Revival of an Unintentionally Abandoned Patent Application under 35 C.F.R. § 1.137(b) with respect to the Parent case, U.S.S.N. 10/456,423. A copy is attached herewith.

Applicants have amended claims 1, 20, 29, and 31. Claim 1 has been amended to include the features shown in figure 1 and Example 1, page 17, lines 15 to 31 through to page 18, lines 1-18. Claim 20 has been amended to recite the composition of the nucleic acid molecule comprised by the cell. Claim 29 has been amended to remove the multiple dependency of the instant claim. Claim 31 depends on claim 29 and has been amended to provide the proper antecedent basis for the term "culturing." No new matter has been added by virtue of these amendments and their entry is respectfully requested.

Claim Objections

Claims 29-36 were objected to under 37 C.F.R. 1.75(c) as being improper form because a multiple dependent claim should refer to other claims in the alternative only.

Applicants have amended claim 29 to remove the multiple dependency. No new matter has been added by virtue of this amendment and its entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant objection.

35 U.S.C. § 102 Rejections

Claims 1-28 are rejected under 35 U.S.C. § 102(e) as being anticipated by Gao *et al.*

Applicants respectfully traverse.

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Applicants invention is directed in part to a nucleic acid molecule comprising a first nucleotide sequence encoding an AAV Rep protein of a first serotype; a second nucleotide sequence encoding an AAV Cap protein of a second serotype; the second serotype being different from the first serotype; and a third nucleotide sequence encoding a transcription product having at least one Adenoviral helper function. The third nucleic acid molecule encoding for the helper function is in the reverse orientation (see, for example, figure 1), whereby these nucleic acids can all be part of the nucleic acid molecule. Furthermore, as amended, claim 1 recites sequences in the nucleic acid molecule which are neither taught or disclosed by Gao *et al.*

Applicants further teach, for example, on page 12, lines 29-30:

Because of tissue tropisms and purification methods described herein, preferred AAV Cap proteins are those derived from serotypes 1 and 5. (Emphasis added).

Applicants select the serotypes based on the desired tissue tropism and the purification method that is disclosed in the instant application. For example, on page 14, lines 24-31:

Purification methods of the invention are particularly useful for purifying virions having capsids containing proteins from AAV serotypes 1 and 5 because these serotypes do not bind to heparin columns. To purify rAAV1 and rAAV5 virions, purification protocols are employed that use iodixanol density gradient centrifugation followed by anion exchange or hydroxyapatite chromatography. Iodixanol is an iodinated density gradient media originally produced as an X-ray contrast compound for injection into humans.

Applicants teach that certain serotypes are desired based on the purification method.

In contrast, Gao *et al.*, do not teach a nucleic acid molecule comprising all three nucleotide sequences. Gao *et al.*, do not teach or disclose the selection of appropriate

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serotype combinations other than generalizations. In fact Gao *et al.*, focus on the serotypes which could potentially be associated with AAV serotype 9. Gao *et al.*, do not teach each and every limitation of the claim 1 and claims dependent therefrom.

In view thereof, reconsideration and withdrawal of the rejection are requested. Accordingly, Applicants submit that the rejection no longer applies to claims 1-28, and respectfully request reconsideration and withdrawal of the rejection.

Claims 1-7 and 9-27 are rejected under 35 U.S.C. § 102(e) and (a) as being anticipated by Fraites *et al.*

Applicants respectfully traverse.

Applicants teach a nucleic acid molecule comprising a first nucleotide sequence encoding an AAV Rep protein of a first serotype; a second nucleotide sequence encoding an AAV Cap protein of a second serotype generated by SEQ ID NO's.: 1-4 ; the second serotype being different from the first serotype; and, a third nucleotide sequence, encoding a transcription product having at least one Adenoviral helper function, in reverse orientation to said first and second nucleotide sequences.

Fraites *et al.*, do not teach or disclose an AAV Rep protein of a first serotype, an AAV Cap protein of a second serotype. That is, Fraites *et al.*, do not teach or disclose the selection of different serotype combinations, nor how to generate AAV that are purified based on their serotypes.

In view thereof, reconsideration and withdrawal of the rejection are requested. Accordingly, Applicants submit that the rejection no longer applies to claims 1-7 and 9-27, and respectfully request reconsideration and withdrawal of the rejection.

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Claims 1-28 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zolotukhin *et al.*

A petition for revival of the parent case has been filed and is attached herewith. Zolotkin *et al.*, are the inventors of the instant invention.

Applicants respectfully request examination on the instant rejection, based on Zolotkin *et al.*, to be withheld pending the outcome of the petition.

Claim Rejections under 35 U.S.C. § 112

Claims 22-28 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as his invention.

Applicants respectfully traverse.

Applicants have amended claims 22-28 to make that which is implicit, explicit. No new matter has been added by virtue of these amendments and their entry is respectfully requested.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection of claims 22-28.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of all rejections and allowance of the application with claims 1-28 are respectfully solicited. The amended claims set forth, herein, are merely to expedite prosecution and allowance of the application and is not to be construed as surrender of any subject matter in the instant application. Applicants hereby reserve the right to pursue the subject matter of the

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canceled claims in one or more continuations, continuation-in-part or divisional patent applications.

If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at telephone number shown below.

Although, Applicants believe that no further extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any extension of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,

AKERMAN SENTERFITT

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